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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/773,351	MAES ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A.SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the arguments filed in the Appeal Brief submitted on October 10, 2006. Applicant's arguments regarding the rejections of the claims over the prior art of record have been fully considered and are persuasive. Accordingly, the rejections of the claims are being withdrawn.

In particular, the Examiner finds that U.S. Patent No. 5,650,166 to Ribier et al does not specifically exemplify a composition having cholesterol sulfate and an exfoliant present in the amount as claimed, and thus does not properly anticipate claims 1 and 3-9. Furthermore, the combination of U.S. Patent No. 5,925,364 to Ribier et al. in view of U.S. Patent No. 5,411,742 to Sebag et al. does not render claims 1, 3-4, 6-9, 11 and 18 obvious, because the references do not provide adequate motivation to combine an exfoliant (i.e. salicylic acid) as taught by Sebag et al. into the composition of Ribier et al. U.S. Patent No. 5,650,166 to Ribier et al. also does not specifically teach or render obvious a composition having the cholesterol sulfate and amino sugar exfoliant in the amounts as claimed, and thus does not render claims 13-20 obvious. Accordingly, these rejections and the rejections of claims 10-12 and 20 over Ribier in view of U.S. Patent No. 6,150,381 to Subbiah and U.S. Patent No. 5,702,691 to Ichinose et al, are being withdrawn.

Claims 1 and 3-20 are pending in the application and are being examined on the merits herein.

The claims are being rejected as follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification as originally filed does not provide adequate support for the recitation that the composition is "an integral mixture" of the cholesterol sulfate and exfoliant/amino sugar, as recited in claims 1, 13, 16 and 19.

The Examiner notes that the claims were previously rejected for reciting the phrase "integral with" in the Office Action mailed on March 23, 2004. In rebutting the

new matter rejection of this phrase, Applicants argued in the response submitted June 23, 2004 that:

"The Examiner admits that "[t]he recitation 'integral with' could be interpreted as 'mixed with' or 'a mixture of' according [sic] its plain and ordinary meaning. Applicants fully agree with this interpretation ..." (page 2 of Amendment Arguments Submitted June 23, 2004.)

Accordingly, the Examiner withdrew the new matter rejection on September 10, 2004, on the grounds that the phrase "integral with" could be understood as meaning "mixed with" or "a mixture of," as argued by Applicants, and thus was understood to encompass any mixture having the components combined together that makes up a single unit, such as a single composition.

However, contrary to this plain meaning of the phrase, Applicants have argued in the response of July 12, 2006 and the appeal brief filed on October 10, 2006, that such "integral mixtures" exclude compositions that have, for example, vesicles, as described by the previously applied Ribier references. Applicants argue that the vesicles in these references are not integrally mixed, but rather are used to form separate and discrete entities present in the aqueous phase. Accordingly, Applicants have indicated that the phrase "integral mixture" can be interpreted to mean a mixture that is without separate and discrete entities, such as vesicles or discrete phases.

The Examiner notes that instant Specification does not provide support under 35 U.S.C. 112, first paragraph, for a definition of "integral mixture" that excludes compositions having vesicles, or two or more phases, as argued by Applicants. Instead, the specification teaches that the composition provides "integrated results" because the two components (exfoliant and cholesterol sulfate) do not cancel out each other's effects (see page 4, lines 21-29.) Thus, the specification specifically refers to "integrated" in the sense that effects provided by each component are not canceled out by one another. The specification does not disclose that such compositions are required to be absent vesicles or multiple phases, and does not otherwise explicitly define "integral" or "integral mixture" to mean that the composition is without discrete phases.

Accordingly, as Applicants have pointed out that the phrase "integral mixture" could be construed as having a meaning that is not fully supported by the specification as originally filed, the claims are being rejected under 35 U.S.C. 112 first paragraph for reciting impermissible new matter, as the specification does not provide support for compositions that are "integral mixtures" in the sense that they do not contain discrete entities or phases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984.

Abe et al. teaches a cosmetic for improving dried skin, preventing aging of skin, providing skin with wetting characteristics, softness and luster by promoting the water retention function of skin, the composition containing cholesteryl sulfate (cholesterol sulfate) and/or its salt (see abstract, in particular.) Abe et al. teaches the cholesterol sulfate or salt thereof can be provided in an amount of from 0.1 to 5 wt% (see abstract, in particular), and thus teaches an amount that meets the range limitation of claims 1 and 13. As Abe et al. teaches the composition is a cosmetic, it is considered that Abe et al. teaches the composition having a cosmetically or pharmaceutically acceptable vehicle, as recited in claims 1 and 13.

Abe et al. does not specifically teach that the composition contains an exfoliant as in claim 1, such as an amino sugar as in claim 5 or 13.

Shimada et al. teaches that cosmetic compositions can containing N-acetylamino sugars or their salts to give smoothness and moist feeling to skin, the amino sugars having an emollient effect, a skin activating effect, and being capable of giving smooth feeling, springiness and luster to the skin (see abstract, in particular.) Shimada et al. teaches that the amino sugars can be N-acetyl-D-glucosamine, N-acetyl-D-galactosamine, and others (see abstract, in particular), and thus teaches the "exfoliant" as recited in claims 1 and 5, and the amino sugar as in claim 13. Shimada et al. also teaches that the N-acetyl amino sugars can be provided in an amount of from 0.1 to 5% by weight of the composition (see abstract, in particular), which is an amount that meets the range limitation as recited in claims 1 and 13.

Accordingly, tit is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the N-acetylamino sugars of Shimada et al. in the cholesterol sulfate-containing composition of Abe et al, because Abe et al. teaches that the cholesterol sulfate composition improves dry skin and wets skin to promote softness and luster of skin, whereas Shimada et al. teaches that the N-acetylamino sugars give smoothness and moistness to skin to improve the feeling and luster of skin. Thus, one of ordinary skill in the art would have found it obvious to provide the N-acetylamino sugars in the composition of Abe et al. with the expectation

of providing an ingredient suitable for moisturizing an improving the luster of skin. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, claims 1 and 13 are considered to be obvious over the teachings of Abe et al. and Shimada et al.

Regarding the recitation that the composition has an "integral mixture" as recited in claims 1 and 13, it is noted that the broadest reasonable interpretation of the composition having an "integral mixture" of the cholesterol sulfate with the exfoliant is that the composition comprises a mixture of the cholesterol sulfate that is formed as a unit with another part of the mixture, which is consistent with the dictionary definition of integral as disclosed in the Merriam-Webster Online Dictionary (formed as a unit with another part <a seat with integral headrest.) Thus, the prior art teaches and/or suggests such a composition, because the prior art teaches or suggests combining the cholesterol sulfate with the exfoliant in a single cosmetic composition (an single unit), and thus the components form an integral mixture in the composition because each part forms a unit (the composition) with another part.

Regarding claim 3, Abe et al. teaches that cholesterol sulfate and salts thereof can be suitably provided (see abstract, in particular), as discussed above. Regarding claim 5, Abe et al. teaches that the N-acetyl amino sugars as claimed can be provided (see abstract, in particular), as discussed above.

Regarding the methods of claims 16 and 19, as Abe et al. and Shimada et al. teach applying the composition containing cholesterol sulfate and the amino sugar to skin, and teach that the composition is capable of improving the condition of skin, including enhancing water retention, preventing aging, and promoting softness and luster of skin, it is considered that the method of Abe et al. and Shimada et al. necessarily also improves or maintains a healthy skin barrier, as recited in claim 16, and necessarily also treats or reduces damage to the skin, where the damage is associated with a reduction or loss of skin barrier function, as recited in claim 19. Since the combined teachings of Abe et al. and Shimada et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the improvement or maintenance of a healthy skin barrier, or the treatment of reduction of damage to skin, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product

does not possess or render obvious the same properties as the instantly claimed product.

Regarding claims 17-18, Abe et al. teaches that the cholesterol sulfate can be provided in an amount of from 0.01 to 5%, preferably 0.05% to 3% (see abstract, in particular), and thus teaches a range that closely overlaps with those claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the cholesterol sulfate provided in the composition, according to the guidance provided by Abe et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, and further in view of JP 05-051314 to Abe et al (hereinafter Abe et al. '314) (machine translation.)

Abe et al. '911 and Shimada et al. are applied as discussed above, and teach a cosmetic composition and method for improving skin by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar.

The references do not specifically teach that the salt of the cholesterol sulfate is potassium.

Abe et al. '314 teaches a cosmetic composition containing ginseng essence and a cholesterol sulfate derivative, such as cholesterol sulfate or its salt (see abstract, in particular.) Abe et al. '314 teaches that suitable salts of the cholesterol sulfate can include the sodium and potassium salts (see paragraphs 0017 and 0023 of machine translation, in particular.) Accordingly, Abe et al. '314 teaches that the potassium salt of cholesterol sulfate is suitable for cosmetic use.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the potassium salt of cholesterol sulfate, as taught by Abe et al. '314 in the composition of Abe et al. '911 and Shimada et al, because Abe et al. '911 and Shimada teach that the cosmetic composition can contain cholesterol sulfate and salts thereof, whereas Abe et al. '314 teaches that the potassium salt is a cosmetically acceptable salt form of cholesterol sulfate. Thus, one of ordinary skill in the art would have been motivated to provide the potassium salt form of the cholesterol sulfate of Abe et al. '911 and Shimada et al, with

the expectation of success in providing a suitable salt form for the cosmetic composition.

Claims 6-9 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, and further in view of WO 90/01323 to Joel E. Bernstein, published February 22, 1990.

Abe et al. '911 and Shimada et al. are applied as discussed above, and teach a cosmetic composition and method for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar.

Abe et al. '911 and Shimada et al. do not specifically teach that the composition contains a fatty acid, as recited for example in claims 6-7 and 14. Abe et al. '911 and Shimada et al. also do not specifically teach that the composition contains cholesterol, as recited for example in claim 8.

Bernstein teaches a composition for treating dry skin that contains a lipid concentrate blended from a combination of three naturally-occurring lipid groups found

in the stratum corneum (see abstract, in particular.) Bernstein teaches that the stratum corneum of the skin contains certain lipids that form a protective "water barrier", and that formulations composed of components of this water barrier can provide treatment of dry skin (see page 1, lines 19-30, in particular.) Bernstein teaches that the lipids can contain one or more of a fatty acids, such as arachidonic, linoleic, linolenic, palmitic, stearic, oleic and docosanoic acids, and sterols such as cholesterol and cholesterol sulfate (see page 2, lines 15-25 and claims 1-4, in particular), and thus teaches topically providing the fatty acids as recited in claims 6-7 and 14, and the cholesterol as recited in claim 8.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the fatty acids and/or cholesterol of Bernstein in the composition of Abe et al. '911 and Shimada et al, because Abe et al. '911 and Shimada et al. teach a composition for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, whereas Bernstein teaches that lipids such as fatty acids and cholesterol can be provided in a topical composition to improve the water barrier function of skin and treat skin dryness. Thus, one of ordinary skill in the art would have been motivated to provide the fatty acids and/or cholesterol in the skin improving/moisturizing composition of Abe et al. '911 and Shimada et al, with the expectation of providing ingredients suitable for relieving dry skin and enhancing the moisture retention of skin. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is

taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding claim 9, Bernstein teaches that suitable lipids can be selected from one or more of fatty acids such a linoleic acid and cholesterol, as discussed above, and thus renders the claim obvious.

Regarding claim 15, Bernstein teaches that a concentrate of the lipids can contain from 25 to 75% of fatty acids, such as linoleic acid, and 10 to 40% of sterols and sterol esters, such as cholesterol (see page 2, lines 15-35, in particular), and teaches that the concentrate can be formulated into topical compositions in a concentration ranging from about 1% to about 50% (see page 2, lines 30-35), and thus teaches a range that overlaps with that in the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of fatty acids such as linoleic acid and/ or cholesterol provided in the composition, according to the guidance provided by Abe et al. '911, Shimada et al. and Bernstein, to provide a composition having desired properties, such as desired moisturization and dry skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover

the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, and further in view of JP Publication No. 10-017458 to Kitada et al, published January 20, 1998 (machine translation.)

Abe et al. '911 and Shimada et al. are applied as discussed above, and teach a cosmetic composition and method for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar.

The references do not specifically teach providing sclareolide in the composition.

Kitada et al. teaches that an essence of plant can be added to a cosmetic composition to provide a composition that improves the uniformity of skin and prevent skin darkness caused by aging (see abstract, in particular.) Kitada et al. teaches that the plant essence may be from Salvia officinalis L, and may include the plant itself, its processed product and/or solvent extract, or solvent-removed extract from drying,

grinding, finely cutting, etc, a part or all parts of the plant (see abstract, in particular.) The Examiner notes that Applicants disclose in their specification that Salvia officinalis L. is a source of sclareolide (see page 6, final full paragraph), and thus it is considered that Kitada et al. teaches providing sclareolide in the form of a plant essence into a cosmetic composition.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sclareolide of Kitada et al. in the cosmetic composition of Abe et al. '911 and Shimada et al, because Abe et al. '911 and Shimada et al. teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Kitada et al. teaches that plant essences such Salvia officinalis L, which contains sclareolide, can be provided in cosmetic compositions to provide skin benefits such as improved skin uniformity and reduced appearance of aging. Thus, one of ordinary skill in the art would have been motivated to provide the sclareolide in the composition of Abe et al. '911 and Shimada et al, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as skin uniformity and anti-aging effects.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, and

further in view of JP 06-263627 to Takahashi et al, published September 20, 1994 (machine translation.)

Abe et al. '911 and Shimada et al. are applied as discussed above, and teach a cosmetic composition and method for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar.

The references do not specifically teach providing the protease inhibitors such as white birch extract in the composition, as recited in claim 11.

Takahashi et al. teaches that a cosmetic for preventing the aging of skin, and that can improve the corneum and impart skin-beautifying effects, among other benefits, contains an extract of a plant belonging to the genus Betula or Alnus of Betulaceae, such as Betula platyphylla (white birch) (see abstract, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the white birch extract of Takahashi et al. in the cosmetic composition of Abe et al. '911 and Shimada et al, because Abe et al. '911 and Shimada et al. teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Takahashi et al. teaches that white birch extract, can be provided in cosmetic compositions to provide

skin benefits such as reduced appearance of aging and skin beautifying effects. Thus, one of ordinary skill in the art would have been motivated to provide the white birch extract in the composition of Abe et al. '911 and Shimada et al, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as anti-aging effects and skin-beautifying effects.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, and further in view of JP Publication No. 10-017458 to Kitada et al, published January 20, 1998 (machine translation) and JP 06-263627 to Takahashi et al, published September 20, 1994 (machine translation.)

Abe et al. '911 and Shimada et al. are applied as discussed above, and teach a cosmetic composition and method for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar.

The references do not specifically teach providing sclareolide and white birch extract in the composition, as recited in claim 12.

Kitada et al. teaches that an essence of plant can be added to a cosmetic composition to provide a composition that improves the uniformity of skin and prevent skin darkness caused by aging (see abstract, in particular.) Kitada et al. teaches that the plant essence may be from Salvia officinalis L, and may include the plant itself, its processed product and/or solvent extract, or solvent-removed extract from drying, grinding, finely cutting, etc, a part or all parts of the plant (see abstract, in particular.) The Examiner notes that Applicants disclose in their specification that Salvia officinalis L. is a source of sclareolide (see page 6, final full paragraph), and thus it is considered that Kitada et al. teaches providing sclareolide in the form of a plant essence into a cosmetic composition.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sclareolide of Kitada et al. in the cosmetic composition of Abe et al. '911 and Shimada et al, because Abe et al. '911 and Shimada et al. teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Kitada et al. teaches that plant essences such Salvia officinalis L, which contains sclareolide, can be provided in cosmetic compositions to provide skin benefits such as improved skin uniformity and reduced appearance of aging. Thus, one of ordinary skill in the art would have been motivated to provide the sclareolide in the composition of Abe et al. '911 and Shimada et al, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as skin uniformity and anti-aging effects.

Abe et al. '911, Shimada et al. and Kitada et al. do not specifically teach providing white birch extract in the composition.

Takahashi et al. teaches that a cosmetic for preventing the aging of skin, and that can improve the corneum and impart skin-beautifying effects, among other benefits, contains an extract of a plant belonging to the genus Betula or Alnus of Betulaceae, such as Betula platyphylla (white birch) (see abstract, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the white birch extract of Takahashi et al. in the cosmetic composition of Abe et al. '911, Shimada et al. and Kitada et al, because Abe et al. '911 , Shimada et al. and Kitada et al. teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Takahashi et al. teaches that white birch extract, can be provided in cosmetic compositions to provide skin benefits such as reduced appearance of aging and skin beautifying effects. Thus, one of ordinary skill in the art would have been motivated to provide the white birch extract in the composition of Abe et al. '911, Shimada et al. and Kitada et al, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as anti-aging effects and skin-beautifying effects. Accordingly, claim 12 is obvious over the teachings of the references.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP Publication No. 60-161911 to Abe et al (hereinafter Abe et al. '911) (English abstract), published August 23, 1985, in view of JP Publication No. 59-013708 to Shimada et al, published January 24, 1984, as applied to claims 1, 3, 5, 13 and 16-19 above, further in view of WO 90/01323 to Joel E. Bernstein, published February 22, 1990, as applied to claims 6-9 and 14-15 above, and further in view of JP Publication No. 10-017458 to Kitada et al, published January 20, 1998 (machine translation) and JP 06-263627 to Takahashi et al, published September 20, 1994 (machine translation.)

Abe et al. '911, Shimada et al. and Bernstein are applied as discussed above, and teach a cosmetic composition and method for improving skin, including reducing aging of skin and enhancing the moisture retention and luster of skin, by providing cholesterol sulfate or a salt thereof and an N-acetyl amino sugar. The references also teach that the composition can contain cholesterol and linoleic acid.

The references do not specifically teach providing sclareolide and white birch extract in the composition, as recited in claim 20.

Kitada et al. teaches that an essence of plant can be added to a cosmetic composition to provide a composition that improves the uniformity of skin and prevent skin darkness caused by aging (see abstract, in particular.) Kitada et al. teaches that the plant essence may be from Salvia officinalis L, and may include the plant itself, its

processed product and/or solvent extract, or solvent-removed extract from drying, grinding, finely cutting, etc, a part or all parts of the plant (see abstract, in particular.) The Examiner notes that Applicants disclose in their specification that Salvia officinalis L. is a source of sclareolide (see page 6, final full paragraph), and thus it is considered that Kitada et al. teaches providing sclareolide in the form of a plant essence into a cosmetic composition.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sclareolide of Kitada et al. in the cosmetic composition of Abe et al. '911, Shimada et al. and Bernstein, because Abe et al. '911, Shimada et al. and Bernstein teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Kitada et al. teaches that plant essences such Salvia officinalis L, which contains sclareolide, can be provided in cosmetic compositions to provide skin benefits such as improved skin uniformity and reduced appearance of aging. Thus, one of ordinary skill in the art would have been motivated to provide the sclareolide in the composition of Abe et al. '911, Shimada et al. and Bernstein, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as skin uniformity and anti-aging effects.

Abe et al. '911, Shimada et al, Bernstein and Kitada et al. do not specifically teach providing white birch extract in the composition.

Takahashi et al. teaches that a cosmetic for preventing the aging of skin, and that can improve the corneum and impart skin-beautifying effects, among other benefits, contains an extract of a plant belonging to the genus Betula or Alnus of Betulaceae, such as Betula platyphylla (white birch) (see abstract, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the white birch extract of Takahashi et al. in the cosmetic composition of Abe et al. '911, Shimada et al, Bernstein and Kitada et al, because Abe et al. '911 , Shimada et al, Bernstein and Kitada et al. teach the composition is suitable for improving the condition of skin, such as reducing aging of skin, and Takahashi et al. teaches that white birch extract, can be provided in cosmetic compositions to provide skin benefits such as reduced appearance of aging and skin beautifying effects. Thus, one of ordinary skill in the art would have been motivated to provide the white birch extract in the composition of Abe et al. '911, Shimada et al, Bernstein and Kitada et al, with the expectation of providing a component capable of imparting skin benefit effects to the composition, such as anti-aging effects and skin-beautifying effects. Accordingly, the combination of these ingredients as recited in claim 20 is considered to be obvious over the teachings of the references.

Regarding the specific amount of each component, as recited in claim 20, it is noted that Abe et al. '911 teaches that the cholesterol sulfate or salt thereof can be provided in an amount of from 0.1 to 5 wt% (see abstract, in particular), and Shimada et al. teaches that the N-acetyl amino sugars can be provided in an amount of from 0.1 to 5% by weight of the composition (see abstract, in particular), which are amounts that closely overlap with the range limitations of claim 20. Bernstein teaches that a concentrate of the lipids can contain from 25 to 75% of fatty acids, such as linoleic acid, and 10 to 40% of sterols and sterol esters, such as cholesterol (see page 2, lines 15-35, in particular), and teaches that the concentrate can be formulated into topical compositions in a concentration ranging from about 1% to about 50% (see page 2, lines 30-35), and thus teaches a range that overlaps with that in the claims. Kitada et al. teaches that the Salvia officinalis L. essence can be provided in a cosmetic in an amount of from 0.001-10 wt% (see abstract, in particular), and Takahashi et al. teaches that the white birch extract can be provided in an amount of fro 0.001 to 2 wt% (see abstract, in particular), and thus teach ranges that closely overlap with those claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of cholesterol sulfate and/or salt thereof, N-acetyl-D-glucosamine, cholesterol, linoleic acid, sclareolide and white birch extract provided in the composition, according to the guidance provided by Abe et al. '911, Shimada et al, Bernstein, Kitada et al. and Takahashi et al, to provide a composition having desired properties, such as desired skin moisturizing, anti-aging, and skin benefit effects. It is noted that "[W]here the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/424,616 for the reasons of record stated in the Office Action mailed August 18, 2006.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the copending application and the instant application are drawn to a skin/cosmetic composition containing cholesterol sulfate, fatty acids, and a sterol (such as cholesterol) and methods employing the compositions. Thus, the copending Application No. 10/424,616 and the instant claims are seen to substantially overlap.

Thus, the instant claims are seen to be obvious over all the claims of copending Application No. 10/424,616.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the rejection of the claims have been considered but are moot in view of the new grounds of rejection.

The Examiner acknowledges Applicant's indication that, if a necessary, a terminal disclaimer will be filed to obviate the provisional obviousness-type double patenting rejection over co-pending Application No. 10/424,616, in the event that

allowable subject matter is indicated. However, as no terminal disclaimer has as-yet been filed, the provisional obviousness-type double patenting rejection is being maintained.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is cited on the accompanying PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

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